REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and these comments.

I. Status of the Claims

Claims 1-26 were cancelled previously. Claims 30 and 42 are cancelled in this response without prejudice or disclaimer thereof. Applicants reverse the right to pursue the subject matter of any cancelled claim in one or more continuing application.

Claim 27 has been amended to incorporate the recitations of claim 30, and with exemplary support in the original specification, at page 3, lines 18-21; at page 5, lines 21-23; at page 8, line 31; and at page 11, lines 10-12. Claims 36-38, 40-41 and 43-44 have been amended for greater clarity and claim 55 has been added accordingly.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 27-29, 31-41 and 43-55 will be pending, with claims 31, 50, 52 and 54 withdrawn from examination.

II. Information Disclosure Statement (IDS)

The examiner asserts that the IDS filed on March 21, 2006 fails to comply with the requirements set forth in 37 C.F.R. 1.98(a)(2). The PTO/SB/08 form accompanying the previously filed IDS is resubmitted herewith, along with the required copies of the cited references. Accordingly, Applicants respectfully request the Examiner consider the IDS and initial and return the PTO/SB/08 form in the next action.

III. Claim Objections

Claims 38 and 43 are subject to objection due to a grammatical error. The claims have been revised to correct the error, and so the basis of the objection is obviated.

IV. Rejection of Claims under 35 U.S.C. §112, second paragraph

Claims 36, 37, 40, 41, 42, and 44 are rejected for alleged indefiniteness. More specifically, the examiner asserts that claims 36, 37, 40, 41 and 44 recite overlapping ranges and that claim 42 is unclear as to "desired" values.

These claims have been amended, where appropriate, to recite the conjunction "or." Consequently, the respective ranges prescribed in the claims are not overlapping.

Without acquiescing to the stated basis of the rejection, claim 42 is cancelled thereby mooting the rejection.

V. Rejection of Claims under 35 U.S.C. §102(b)

Claims 27, 29, 30, 33-35, 38-41, and 44 stand rejected for alleged anticipation by U.S. Patent No. 3,930,028 to Ullmann *et al.* Applicants respectfully traverse the rejection.

The claimed invention relates to a process of large-scale production of lactobionic acid. See specification, page 3, lines 19-21; page 5, lines 21-23. Specifically, the claimed invention entails a process of producing lactobionic acid in a dairy product. The process is carried out with the pH maintained, by addition of a weak base, between 3.0 and 9.0 and achieves an increased yield and a reduced reaction time in an enzymatic conversion of lactose to lactobionic acid.

As to this process, with lactobionic acid as the end product, Ullmann's teachings are essentially irrelevant because they relate to eliminating dry solids from the diary waste, milk serum, by fermentation with certain *Enterobacter* or *Serratia* strains. Thus, Ullmann does not meet the claims recitations, *e.g.*, for "producing lactobionic acid," whereby "an increased yield" and "a decreased reaction time" in converting lactose to lactobionic acid are achieved, and for the maintenance of pH within a prescribed range during the process.

For the examiner, Ullmann's mention of including a lactose oxidase means that "lactose oxidase catalyzes the conversion of lactose to lactobionic acid" in the prior-art process and that "the product … is lactobionic acid." Office Action at page 8, lines 3-5. Even were the examiner's

interpretation taken at face value, however, Ullman still would not have conveyed to the skilled artisan the sense of a process for optimizing lactobionic acid yield.

This is so because Ullmann nowhere mentions how or even whether to obtain lactobionic acid as a conversion product. Instead, Ullmann aims at eliminating the solids in the dairy waste by its disclosure that "most of the lactose and of the lactalbumin have ***disappeared*** after 48 hours" (column 5, lines 18-20; emphasis added). This teaching would not have counseled one of ordinary skill in the art to "produce lactobionic acid," as prescribed by the present claims. Ullmann is silent, too, as to how to increase the yield or how to decrease the reaction time in the enzymatic conversion.

The foregoing identifies ample basis for withdrawal of the subject rejection. Still, the examiner also contends that Ullmann meets the claim recitation of "maintaining pH" during the process. Applicants respectfully disagree.

The examiner improperly invoked the "inherency" doctrine to substantiate the rejection. According to the examiner: (i) the product of Ullmann's process is lactobionic acid simply because lactose oxidase is added in Ullmann's process of eliminating solids in the dairy waste; (ii) Example 3 shows improved level of lactose conversion; and, since the pH of Ullmann is kept at between pH 6 and pH 7, (iii) Ullmann necessarily ("inherently") teaches increased lactobionic acid production under maintained pH condition.

This rationale is flawed in several aspects, however. First, in Ullmann's disclosure of eliminating solids in the dairy waste there is no suggestion, not to mention a teaching, that would have implicated obtaining (*i.e.*, producing and collecting) lactobionic acid, let alone that product with an increased yield and a reduced reaction time. Second, Example 3 of Ullmann would not have indicated, necessarily or otherwise, an improved level of lactose conversion and, hence, at increased production of lactobionic acid. In fact, Example 3 demonstrates that, when the incubation time with the *Enterobacter* strain 671 was prolonged from 24 hours to 46 hours, higher percentage of protein and higher percentage of sugar were eliminated from the dairy waste, resulting in less solid in the waste, i.e., the solid is reduced from 3.3 g/100 ml to 1.5 g/100 ml.

Thus, Ullmann's "maintenance" of pH is in a context wholly irrelevant to that of the claimed invention, namely, the context of producing lactobionic acid. Accordingly, the examiner can only make the rejection by extracting claim elements from the prior art, out of context, and then reassembling them with the aid of impermissible hindsight.

Because the rejection is based on a faulty rationale, withdrawal of the rejection is warranted.

VI. Rejection of Claims under 35 U.S.C. §103(a)

A. Ullmann and Lynglev

Claims 27, 29, 30, 33-44, 48, and 49 are rejected obvious over Ullmann and U.S. published application 2003/0113405 to Lynglev. Applicants respectfully traverse the rejection.

Ullmann is discussed above. The examiner cites Lynglev for the alleged teaching of a carbohydrate oxidase from *Microdochium* and for the added amount of that enzyme. See Office Action at page 12, lines 15-17. Examiner Macauley asserts that Ullmann teaches "treatment of a dairy substrate using nearly the same process as is recited in the instant claims," and that "[i]t was also known that a method for the production of lactobionic acid could use the enzyme recited in the claims" (*id.* at page 13, lines 6-10). Therefore, "[o]ne of ordinary skill in the art would have been motivated to combine these methods because Lynglev is directed to the improvement of the process of diary products by the conversion of lactose to lactobionic acid and Ullmann teaches that the oxidation of lactose is enhanced by controlling the pH of the reaction mixture" (*id.*, lines 10-13).

As demonstrated above, however, Ullmann is irrelevant to "treatment of a dairy substrate" or "a method for the production of lactobionic acid," the examiner's contrary contention notwithstanding. Rather, Ullmann relates to eliminating the solids in dairy waste. Lynglev is directed to producing a fermented dairy product with improved organoleptic properties, such as less firmness and/or sourness (see abstract). Accordingly, one of ordinary skill would have had no reason to draw on a teaching on eliminating dairy waste (Ullmann), in view of a teaching about improving organoleptic properties of a dairy product (Lynglev), for guidance on producing lactobionic acid.

Secondly, Ullmann merely discloses neutralizing the acidic diary waste before bacteria fermentation, thereby to eliminate the solids (see column 4, lines 61-68). This teaching in no way supports the examiner's position that "Ullmann teaches that the oxidation of lactose is enhanced by controlling the pH of the reaction mixture."

Accordingly, the examiner's articulated motivation to combine the references lacks factual support in the art.

Thirdly, as discussed in the foregoing paragraphs, Ullmann makes no disclosure, implicit or explicit, about "enhancing oxidation of lactose," and so there could have been no suggestion, let alone a teaching, of an impact in that regard of controlling pH.

The Examiner goes on to assert that, "since Ullmann teaches the maintenance of pH under various conditions, it is expected that the maintenance under the claimed oxygen conditions would be performed or would have been achieved in the course of routine experimentation" (*id.*, page 13, lines 16-19). Again, the Examiner's assertion lacks any context that might render it pertinent to a proper Section 103 analysis of Applicants' claimed invention. In particular, "routine experimentation" has no meaning outside the context of a specific process under consideration (here, lactobionic acid production)

Ullmann at the most discloses adjusting pH during a process of eliminating solid in a dairy waste, but this is irrelevant to a process of producing lactobionic acid under certain oxygen conditions. In the absence of any connection between these two unrelated processes, one of ordinary skill would have no reason to pursue lactobionic acid production in view of the prior-art teachings.

Even if there had been some reason for the posited combination of references, moreover, the person of ordinary skill would not have been led thereby to the presently claimed invention. This is so because Lynglev's process is targeted on achieving certain firmness and/or sourness of the dairy product. So informed, one of ordinary skill could not have suspected that an increased yield in enzymatic conversion of lactose to lactobionic acid could be achieved by incubating the dairy substrate in the presence of the carbohydrate oxidase under maintained pH conditions.

It is apparent, therefore, that the examiner can only substantiate this rejection by knowing about the claimed invention itself. Moreover, the examiner is silent about how the combined teachings of the cited references could meet the recited "obtaining a decreased reaction time in enzymatic conversion." Accordingly, Applicants respectfully request withdrawal of the rejection.

B. **Ullmann, Lynglev and Koka**

Claims 27-29, 30, 32-44, 48, and 49 stand rejected for asserted obviousness over Ullmann in view of Lynglev and WO 02/089292 to Koka. Applicants respectfully traverse the rejection.

The teachings of Ullmann and Lynglev are discussed above. Koka is cited for the alleged teaching of purification of lactobionic acid and maintaining the pH with $CaOH_2$. Office Action, page 14, 2nd full paragraph.

The examiner states: "since Ullmann and Lynglev teach improved methods for the production of lactobionic acid, one would have recognized that the produced acid could have been separated and used in a different process" (Office Action, page 15, lines 4-6). Contrary to the examiner's assertion, however, neither Ullmann, directed to eliminating solids in dairy waste, nor Lynglev, directed to improving firmness and/or sourness of a fermented dairy product, teaches an improved method for the production of lactobionic acid.

Koka also does not disclose purifying the lactobionic acid, as claim 28 prescribes. Rather, Koka teaches making diary products, such as cheeses, by adding lactobionic acid. The lactobionic acid can be in a purified form, from an extraneous source or, alternatively, can be produced *in situ* in the dairy product by adding a lactose oxidase (abstract). In other words, Koka relates to the ***use*** of lactobionic acid in manufacturing a dairy product rather than to ***purification*** of lactobionic acid.

C. **Ullmann, Lynglev and Rand**

Claims 27, 29, 30, and 33-49 are rejected over Ullmann in view of Lynglev and Rand, *J. Dairy Science* 58: 1144-50 (1974). Applicants respectfully traverse the rejection.

The teachings of Ullmann and Lynglev are discussed above. Rand is cited for the alleged teaching of addition of a catalase and hydrogen peroxide to provide oxygen to the enzymatic conversion. Rand fails to compensate for the deficiencies of Ullmann and Lynglev, however, as the foregoing paragraphs discuss.

D. Unexpected Results

The patentability of the claimed invention is substantiated, too, because it achieves results that the skilled artisan would have considered wholly unexpected, given the prior art of record. As described in Example 5, when different bases were used in the conversion of lactose to lactobionic acid, a weak base was able to complete the conversion in approximately 4.5 hours, much shorter than over 6 hours required for a strong base. There was no principle or empirical result known to the art that would have presaged this effect of a weak basis, pursuant to the claimed invention.

VII. Provisional Double Patenting Rejection

Claims 27-30, 32-49, 51, and 53 are rejected over claims 1-15 of co-pending, commonly owned application serial No. 11/621,819, in view of Ullmann and Lynglev. Because the rejection is provisional, however, Applicants choose to defer any action until the claims are otherwise allowable.

CONCLUSION

Applicants submit that the present application is in condition for allowance, and they request an early indication to this effect. Examiner Macauley is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

Respectfully submitted,

Date June 24, 2010

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The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of the relevant fee(s) from the deposit account.